

SafeBoosC-IIIv Steering Committee meeting

15th January 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Mathias Lühr Hansen (Copenhagen Trial Unit), Merih Cetinkaya (Turkey), Renato Procianoy (Brazil), Gitte Hahn (Denmark), Gorm Greisen (Denmark), Hans Fuchs (Germany), Jyoti Lakhwani (Zambia), Gabriel Dimitriou (Greece), Eugene Dempsey (Ireland), Jorge Fabres (Chile), Monica Fumagalli (Italy), Jakub Tkaczyk (Czech Republic), Saudamini Nesargi (India).

Apologies: Cornelia Hagmann (Switzerland), Siv Fredly (Norway), Livia Ognean (Romania), Tomasz Szczapa (Poland), Gunnar Naulaers (Belgium), Adelina Pellicer (Spain).

Absent: Lina Chalak (US), Laishuan Wang (China), Fernando Silvera (Uruguay), Gerhard Pichler (Austria), Daniel Virella (Portugal), Gabriel Musante (Argentina), Atul Malhotra/Himanshu Popat (Australia).

Moderator: Caroline Kamp

Minute taker: Johanne Juul Petersen

1) Approval of the agenda

Agenda approved.

2) Members of the Steering Committee

Caroline went through the list of national coordinators. Since the last Steering Committee meeting, Caroline and Johanne have met with Massimo Di Maio from France, who was interested in joining as principal investigator. There is still no national coordinator in France, but Gorm has contacted Jean-Christophe Roze. Mathias has talked to Anne Marie from the UK, and they need funding before the UK can join. Gene will reach out to a few contacts in Liverpool.

3) Central updates

Caroline gave an update on the final central steps before randomisation. These included the following:

a. Ethical approval

Ethical approval was obtained in Denmark on the 13th of January. This will be sent to everyone for ethical approval in the remaining countries.

b. eCRF

The eCRF is being finalised with input from the Executive Steering Committee. It will be ready within a few weeks.

c. Standard operating procedures

A lot of standard operating procedures have been updated. These are available on the website.

d. Web-based training

Marie is finalising the web-based training based on the material from SafeBoosC-III. It will be available on the website within a few weeks.

e. Local data monitoring

The local data monitoring plan and templates for initiation and monitoring visits are available on the website.

f. Ready for randomisation

All central steps will be ready for randomisation to start on the 1st of February.

g. Statistical analysis plan and protocol paper

Copenhagen Trial Unit will work on the statistical analysis plan and protocol paper in the following months.

h. Website: safeboosc.eu

Caroline showed the website.

4) National Coordinator update

- **Renato, Brazil:** Waiting for ethical approval. Interest from nine centres. OxyPrem will lend equipment to the centres.
- **Gunnar, Belgium:** Waiting for ethical approval. No funding has been obtained yet. Three/four centres are interested despite no funding.
- **Hans, Germany:** Waiting for ethical approval. Interest from two centres. After ethical approval has been obtained, the contracts need to be done, which might take some time.
- **Merih, Turkey:** Waiting for ethical approval. Interest from five centres.
- **Gabriel, Greece:** Waiting for ethical approval. Interest from five centres. Some centres need equipment. Waiting for contact to OxyPrem.
- **Jorge, Chile:** Interest from 14 centres. Each centre will need individual ethical approval.
- **Jyoti, Zambia:** Waiting for ethical approval. Interest from three centres.
- **Saudamini, India:** Interest from four centres. Two centres have ethical approval.
- **Eugene, Ireland:** Interest from two centres. Gene is working on sorting out funding.
- **Jakub, Czech Republic:** Waiting for ethical approval. Maybe one additional centre will join.
- **Monica, Italy:** Waiting for ethical approval. Looking for funding.
- **Gitte, Denmark:** Ethical approval has been obtained. Interest from two centres.
- **Adelina, Spain:** Not present. Updated on email. Interest from 12 centres. Five centres have received ethical approval, and five centres have signed contracts.
- **Tomasz, Poland:** Not present. Will update on email.

5) Any other business

Next Steering Committee meeting will be 19th of March 2025, 20:30 CET.

Substudy meeting 5th of February 2025, 20:30 CET. Substudies can be presented at this meeting. A Standard Operating Procedure on substudies is available on the website.